

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1.-13. (Canceled)

14. (Currently Amended) A method for determining the presence of a lung cancer in a patient, comprising the steps of:

- (a) obtaining a biological sample from the patient;
- (b) contacting the biological sample with an oligonucleotide that hybridizes to a sequence set forth in SEQ ID NO:1797, or a complement thereof, under ~~moderately highly~~ stringent conditions;
- (c) detecting in the sample an amount of an expressed polynucleotide that hybridizes to the oligonucleotide; and
- (d) comparing the amount of polynucleotide that hybridizes to the oligonucleotide to a predetermined cut-off value, and therefrom determining the presence of the cancer in the patient.

15.-18. (Canceled)

19. (Currently Amended) A method for monitoring the progression of a lung cancer in a patient, comprising the steps of:

- (a) contacting a biological sample obtained from the patient with an oligonucleotide that hybridizes to a sequence set forth in SEQ ID NO:1797, or a complement thereof, under ~~moderately highly~~ stringent conditions;
- (b) detecting in the sample an amount of an expressed polynucleotide that hybridizes to the oligonucleotide;
- (c) repeating steps (a) and (b) using a biological sample obtained from the patient at a subsequent point in time; and
- (d) comparing the amount of expressed polynucleotide detected in step (c) to the amount detected in step (b), and therefrom monitoring the progression of the cancer in the patient.

20. (Currently Amended) A method for determining the presence of a lung cancer in a patient comprising:

- (a) obtaining a biological sample from the patient;
- (b) contacting the sample with at least two oligonucleotide primers in a reverse transcription polymerase chain reaction, wherein said oligonucleotide primers are effective for amplifying a polynucleotide sequence of SEQ ID NO:1797 and ~~hybridize to a sequence set forth in SEQ ID NO:1797, or a complement thereof, under highly stringent conditions;~~
- (c) detecting in the sample an amount of amplified polynucleotide sequence; and

(d) comparing the amount of amplified polynucleotide to a control value, and therefrom determining the presence of the cancer in the patient.

21. (Previously Presented) The method of claim 20, wherein the oligonucleotide primers comprise at least 10 contiguous nucleotides of SEQ ID NO:1797.

22. (Previously Presented) The method of claim 14, wherein the biological sample is selected from the group consisting of: lung tissue, blood, sera, sputum, urine, and a tumor biopsy.

23. (Currently Amended) The method of claim ~~1819~~, wherein the biological sample is selected from the group consisting of: lung tissue, blood, sera, sputum, urine, and a tumor biopsy.

24. (Previously Presented) The method of claim 20, wherein the biological sample is selected from the group consisting of: lung tissue, blood, sera, sputum, urine, and a tumor biopsy.

REMARKS

Favorable reconsideration of the subject application is respectfully requested in view of the above amendments and the following remarks. Claims 1-13 and 15-18 were canceled in the prior amendment filed April 7, 2003, thus, claims 14, and 19-24 are under consideration. Claims 14, 19, and 20 have been amended to more specifically recite certain aspects of the invention, and claim 23 has been amended to correct dependency. Support for these amendments may be found throughout the specification and claims as originally filed, and it is urged that the amendments do not constitute new matter. Specific support for the use of highly stringent hybridization conditions is provided, *e.g.*, on page 87, lines 3-16. It should also be noted that the above amendments are not to be construed as acquiescence with regard to the Examiner's rejections and are made without prejudice to prosecution of any subject matter removed or modified by this amendment in a related divisional, continuation or continuation-in-part application. Lastly, Applicants wish to thank the Examiner for withdrawing the previous enablement rejection.

Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 14 and 19-24 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. More specifically, the Action asserts that the instant specification does not adequately describe the genus of polynucleotides that hybridize under moderately stringent conditions to a polynucleotide having the sequence of SEQ ID NO:1797, since "no common element or attributes of the sequences are disclosed," and "no structural limitations or requirements which provide guidance on the identification of sequences which meet these functional limitations is provided." In addition, the Action indicates that the currently claimed limitation regarding "moderately stringent hybridization conditions" permits significant variation relative to the specific sequence described in SEQ ID NO:1797 and asserts that there is no function required of the claimed oligonucleotides. The Action also asserts that

the definition of the oligonucleotides is significantly functional with no specific structure whatsoever required by the claims.

Applicants respectfully traverse this rejection and submit that the instant claims satisfy the written description requirement of 35 U.S.C. § 112, first paragraph.

Applicants submit that the instant invention is related to the discovery that the lung tumor antigen having the polynucleotide sequence set forth in SEQ ID NO:1797 (referred to as L978P) is overexpressed in lung tumor tissue and, consequently, can be used for a variety of purposes, including the diagnosis and detection of lung cancer. Applicants further submit that the skilled artisan would clearly understand that Applicants were, thus, in possession of methods related to examining the expression levels of L978P polynucleotides, including the claimed methods using oligonucleotides capable of hybridizing under moderately stringent conditions to the polynucleotide sequence of SEQ ID NO:1797 or effective for amplifying a polynucleotide sequence of SEQ ID NO:1797. Applicants submit that the instant claims are analogous to method claims requiring the use of an antibody to examine expression levels of polypeptides, wherein it is understood that the skilled artisan would appreciate that the inventors had possession of the method absent the disclosure of the structure of even one antibody within the claimed genus. Applicants further submit that the skilled artisan would be readily able to recognize oligonucleotides having this ability, based upon the teachings of the specification, including the disclosure of the nucleotide sequence of SEQ ID NO:1797. In addition, Applicants note that claim 24 is limited to the use of oligonucleotides primers comprising at least 10 contiguous nucleotides of the species of SEQ ID NO:1797. Therefore, Applicants submit that the skilled artisan would recognize that Applicants had possession of the instant method claims at the time of filing, and, accordingly, the written description requirements is satisfied for the instant claims.

However, to expedite prosecution of the instant application and without acquiescence to this basis of rejection, Applicants have amended the claims to require that the oligonucleotides hybridize to a sequence set forth in SEQ ID NO:1797, or a complement thereof, under highly stringent conditions, rather than moderately stringent conditions. Support for the use of highly stringent hybridization conditions is provided, *e.g.*, on page 87, lines 3-16. As

recognized in the Office Action (page 6), this amendment requires the oligonucleotides to be more similar in structure to polynucleotides having a sequence set forth in SEQ ID NO:1797 and provides a clear structural definition of oligonucleotides used according to the claimed methods. In addition, Applicants submit that the requirement that the oligonucleotides hybridize to a sequence set forth in SEQ ID NO:1797 further provides a descriptive functional definition of these oligonucleotides.

Applicants submit that under the Examination Guidelines set forth by the Patent and Trademark Office, the written description requirement for a claimed genus may be satisfied by the description of a representative number of species or the disclosure of relevant, identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. Guidelines for Examination of Patent Applications under the 35 U.S.C. § 112, ¶1, “Written Description” Requirement, 66 Fed. Reg. 1099, at 1106. Applicants note that the Examination Guidelines clearly provide that acceptable identifying characteristics include both sequence and binding affinity. *Id.* at 1110. In fact, the examples provided in the Guidelines of sufficiently detailed, relevant identifying characteristics that provide evidence that applicant was in possession of the claimed invention include, “complete or partial structure....functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of these characteristics.” *Id.* at 1106.

Applicants submit that the instant specification discloses sufficient identifying characteristics for oligonucleotides capable of hybridizing to a sequence set forth in SEQ ID NO:1797 under highly stringent conditions, since it provides both a structural characteristic, *e.g.*, the reference sequence of SEQ ID NO:1797, and a functional characteristic, *e.g.*, the ability to hybridize to a sequence set forth in SEQ ID NO:1797 under highly stringent conditions, for the claimed oligonucleotides. Applicants submit that this combination of structural and functional characteristics clearly satisfies the requirements set forth in the Examination Guidelines and establishes that Applicants were in possession of the claimed invention. In light of the above amendments and remarks, Applicants respectfully request that this basis of rejection be withdrawn.

Application No. 09/849,626
Reply to Office Action dated July 11, 2003

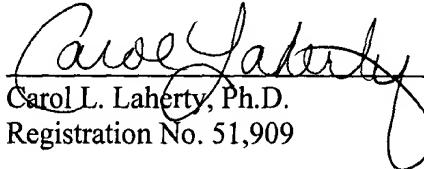
The Commissioner is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Applicants respectfully submit that all of the claims remaining in the application are allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

Chaitanya S. Bangur et al.

SEED Intellectual Property Law Group PLLC



Carol L. Laherty, Ph.D.
Registration No. 51,909

Enclosure:
Postcard

701 Fifth Avenue, Suite 6300
Seattle, Washington 98104-7092
Phone: (206) 622-4900
Fax: (206) 682-6031
400175_1.DOC